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EXAMINER
PAPAPIETRO, JACQUELINE M

ART UNIT	PAPER NUMBER
3739	

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12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/756,173

Applicant(s)

ZANELLI ET AL.

Examiner

Jacqueline Papapietro

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-10 and 12-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-10 and 12-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 depends on claims 4 and 8, which are method claims. Claim 24 claims a system. Claim 24 will be examined as if dependent on claim 20. However, correction and clarification is required. R 25

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-10, 18-23, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (US 205/0143677 A1) in view of Watkins et al (US 5769790).

Young discloses a method for removing hair from a patient's skin (paragraph 0035), said method comprising: transcutaneously focusing high intensity acoustic energy (paragraph 0014 lines 6-7) at hair follicles beneath the skin (paragraph 0021 lines 3-4), wherein the acoustic energy is focused at predetermined follicle location

(paragraph 0024). Young is silent regarding how the locations and depths of the follicles are determined.

Watkins teaches a method for delivering therapeutic ultrasound to a desired location, wherein ultrasound imaging is used to localize a target volume prior to applying therapeutic levels of ultrasound imaging (column 2 lines 26-35). The method comprises scanning an acoustic transducer (28, Fig 1) over an area in the patient to identify target locations and volumes (which includes depths, column 2 lines 44-62); and transcutaneously focusing high intensity acoustic energy at the identified targets (column 4 lines 43-50). Watkins teaches the method wherein a single acoustic transducer is used both to scan/image and to deliver the focused high intensity acoustic energy (26', Fig 2, column 6 lines 20-21); or wherein different acoustic transducers are used (26 and 28, Fig 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Young by scanning an acoustic transducer, either distinct or the same as the therapeutic transducer, over the desired area as taught by Watkins in order to locate the desired treatment sites (the hair follicles).

Regarding claims 8-10, Watkins teaches immobilizing a transducer platform (38, Fig 2) over a target area, and completing the steps are described above, further comprising the step of selecting individual targets to be ablated from the plurality of imaged targets (column 2 line 63- column 3 line 10). The transducer is mechanically advanced in X- and Y- directions over an imaging plane to known coordinates by a positioning system (38) and controller (12, Fig 3). Because the imaging transducer is

the therapeutic transducer, the scanning and positioning transducers are advanced to the same coordinates. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the positioning system as taught by Watkins in the method of Young in view of Watkins, as described above in order to accurately position the transducer(s).

Regarding claims 18 and 19, Watkins further teaches producing an image of the scanned area and designating which target areas are to be ablated (column 4 lines 46-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the steps of producing an image of the scanned area and designating which hair follicles should be ablated, as taught by Watkins, in the method of Young, in order to precisely determine target locations for the high intensity focused acoustic energy.

Regarding claims 20-22, 27, and 28, Young discloses a system for hair removal comprising: a transducer (as described above, but does not disclose imaging hair follicles or tracking the location of the transducer. Watkins teaches a system for focused ultrasound therapy, said system comprising: a transducer (26) selectively operable to image a target zone and to acoustically ablate hair follicles at said target zones (the target zones being hair follicles); means for tracking a position of the transducer over a patient's skin surface (positioning system, 38); and a controller (12, Fig 3) for acquiring image data from the transducer including the depth and location of each target (column 2 line 63- column 3 line 10) and for directing high intensity acoustic energy (see Fig 3) to selected ones of the imaged target zones (hair follicles); wherein the tracking means

comprises a transducer platform (38, Fig 2) adapted to be engaged against the patient's skin; and a drive system (mechanical positioning system, column 3 lines 50-52) for advancing the transducer over a planar region defined by the platform (the mechanical positioning system has three or more axes of motion, but could be advanced in the X- and Y-directions only), wherein the position of the transducer can be both selected and recorded (column 4 lines 39-50). Watkins also teaches the system further comprising a display which provides a visual depiction of the target zone (22) and means for a user to designate which of the areas in the visual depiction are to be ablated (column 2 lines 44-49 and 63-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the focused ultrasound system taught by Watkins in the hair removal system of Young in order to precisely target and ablate the desired hair follicles.

Regarding claim 23, Watkins is silent regarding the accuracy of the positioning system. It would have been obvious to make the motion position very accurate and repeatable to + 0.01 mm due to the small size of the hair follicles being targeted and ablated.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Watkins as applied to claim 4 above, and further in view of Martin et al (US 6432067 B1).

Young in view of Watkins discloses the method as in claims 4 and 8, but is silent regarding the method of transcutaneously focusing. Martin teaches a method for

utilizing high intensity focused ultrasound wherein focusing comprises adjusting the depth of focus by translating a transducer along a vertical line (column 10 lines 55-58). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the focusing method as taught by Martin in the method of Young in view of Watkins in order to focus the acoustic energy on the desired hair follicle location.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Watkins as applied to claim 4 above, and further in view of Weng et al (US 6719694 B2).

Young in view of Watkins discloses the method of claims 4 and 8, but is silent regarding the method of transcutaneously focusing. Weng teaches a method for focusing high intensity acoustic energy comprising adjusting the depth of focus by adjusting the curvature of a transducer surface (column 11 lines 58-61, Fig 13A) and by controlling the operation of a phased array transducer (column 15 lines 32-35, Figs 17A-17C). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the focusing methods as taught by Weng in the method of Young in view of Watkins in order to focus the acoustic energy on the desired hair follicle location.

Claims 15-17 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Watkins as applied to claims 4, 8 and 20 above, and further in view of Masotti (WO 02/09813 A1).

Young in view of Watkins discloses the method as in claims 4 and 8 and the system of claim 20, but no depth for focusing the high intensity acoustic energy is disclosed. Masotti teaches applying ultrasonic waves to a hair follicle wherein the high intensity acoustic energy is focused at a depth beneath the skin the range from 1 mm to 6 mm and at a width in the range from 0.1 mm to 0.3 mm (page 12, lines 12-14), wherein the high intensity acoustic energy is delivered under conditions to raise the temperature at the hair follicle to at least 50°C (page 6 line 31), wherein the energy is delivered in an amount from 0.1 J to 10 J (page 12 lines 8-9) for a time of at least 0.1 sec (page 12 lines 9-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Young in view of Watkins by focusing and delivering the acoustic energy as taught by Masotti in order to effectively ablate the targeted follicle.

Response to Arguments

Applicant's arguments filed September 27, 2007 have been fully considered but they are not persuasive.

Applicant argues that Young in view of Watkins does not disclose the method as claimed. Applicant states that the scanning and targeting method of Watkins "would be impractical or more than likely impossible for treating hundreds of thousands of hair

follicles." However, Applicant has not claimed that hundreds or thousands of hair follicles are being treated, only a plurality of hair follicles. Watkins clearly teaches that a plurality of locations can be targeted (i.e. "at each treatment location," column 4 line 51). Therefore, a plurality of target locations and depths are indeed identified. Examiner maintains that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined Young and Watkins to arrive at Applicant's invention as claimed.

Regarding the teachings of Masotti, Figure 1 clearly shows that the ultrasonic energy is focused as a location beneath the skin (see page 4 lines 8-14). Masotti teaches that it is old and well known in the art to apply ultrasonic waves to a hair follicle wherein the high intensity acoustic energy is focused at a depth beneath the skin the range from 1 mm to 6 mm and at a width in the range from 0.1 mm to 0.3 mm (page 12, lines 12-14), wherein the high intensity acoustic energy is delivered under conditions to raise the temperature at the hair follicle to at least 50°C (page 6 line 31), wherein the energy is delivered in an amount from 0.1 J to 10 J (page 12 lines 8-9) for a time of at least 0.1 sec (page 12 lines 9-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Young in view of Watkins by focusing and delivering the acoustic energy as taught by Masotti in order to effectively ablate the targeted follicle.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

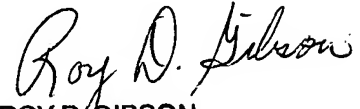
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Jacqueline Papapietro
Art Unit 3739



ROY D. GIBSON
PRIMARY EXAMINER